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(73) Patenthaver: **Intersurgical AG, Landstrasse 11, Vaduz, Liechtenstein**
Dr Nasir, Muhammed Aslam, Top Valley Lodge , Chaul End Village , Caddington, Luton, Bedfordshire LU1 4AX, Storbritannien

(72) Opfinder: **KEMP, Jane Elizabeth, 514 Armidale Place, Bristol BS6 5DA, Storbritannien**
MILLER, Andrew Neil, 4 Knowles Avenue, Crowthorne RG45 6DU, Storbritannien
NASIR, Muhammed Aslam, Dr., Top Valley Lodge, Chaul End Village, Caddington, Luton, Bedfordshire LU1 4AX, Storbritannien

(74) Fuldmægtig i Danmark: **NORDIC PATENT SERVICE A/S, Bredgade 30, 1260 København K, Danmark**

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DESCRIPTION

Field of the Invention

[0001] The present invention relates to medical devices and is applicable to laryngeal airway devices and to their methods of manufacture. It is particularly applicable to devices used in the administration of Oxygen and/or anaesthetic gases to a human or veterinary patient breathing spontaneously, for Intermittent Positive Pressure Ventilation (IPPV) during a surgical procedure or resuscitation and for intubating patients during such procedures.

Background to the Invention

[0002] GB2393399 (Nasir) describes an airway device comprising an airway tube having a first end and a second end, the first end of which is surrounded by a non-inflatable laryngeal cuff which forms an anatomical fit over the laryngeal inlet of a patient and a buccal cavity stabiliser located on or around the airway tube between the laryngeal cuff and the second end of the tube, the buccal stabiliser being adapted to prevent rotational or side-to-side movement of the airway device in use.

[0003] Whilst such airway devices provide a significant improvement over the use of inflatable cuff airway devices, it is still sometimes necessary to intubate a patient during a procedure.

[0004] A number of attempts have been made to provide for an airway device which not only forms an external seal around the laryngeal inlet of the patient, but also serves as a guide to allow for the insertion of an endotracheal tube. However, such devices have always been inflatable, do not always provide for the endotracheal tube to be guided directly into the laryngeal inlet and instead can direct the endotracheal tube into the oesophagus of the patient, and can cause the airway tube of the airway device to become blocked cutting off the air supply to the patient.

[0005] US2009/0090356 (COOK DANIEL J) describes a supralaryngeal airway of the type used to facilitate lung ventilation and the insertion of endo-tracheal tubes or related medical instruments through a patient's glottis where the shield is constructed to include a protrusion which serves to direct instruments inserted through the airway away from the proximal base of the shield and into the glottis of the patient.

[0006] US5896858 (BRAIN ARCHIBALD IAN JEREMY) describes an artificial airway device to facilitate a patient's lung ventilation comprises an airway tube and a laryngeal mask at one end of the tube. The mask is of generally elliptical configuration, with an inflatable peripheral cuff of flexible material around the edges of the mask, for sealed support of the mask around the inlet to the patient's larynx. The mask has an aperture through which the airway tube opens into the

interior of the mask. The mask also comprises a longitudinally directed bar, extending across the mask aperture, from the central upper edge or rim of the mask aperture, to which it has effectively a hinged attachment, to the posterior rim of the mask aperture, at which the bar is free. The hinged mounting of this bar is so positioned at longitudinal offset from the distal end of the mask (which locates in the upper sphincter or oesophageal inlet) that the introduction of an inserted endotracheal tube will automatically engage and swing the bar backward into camming engagement with the epiglottis, thus easily folding the epiglottis backward against the wall of the laryngeal inlet and permitting undeflected insertional passage of the endotracheal tube to and through the laryngeal inlet, and permitting undeflected insertional passage of the endotracheal tube to and through the laryngeal inlet.

Summary of the Invention

[0007] The present invention provides an airway device as defined in the accompanying claims.

[0008] Accordingly, according to a first aspect of the present invention, there is provided an airway device for human or animal use comprising an airway tube having a first end and a second end, the first end of which is surrounded by a laryngeal cuff configured to fit over the laryngeal inlet of a patient when in situ, wherein the first end of the airway tube is provided with an intubating ramp configured to direct a tube inserted through the airway tube into the laryngeal inlet of the patient when in situ wherein the airway tube comprises an internal wall, the internal wall comprising a ventral side and a dorsal side, and wherein the internal wall of the ventral side of the first end of the airway tube is flattened rather than curved and wherein the first end of the airway tube is of greater diameter than a remainder of the airway tube. Preferably the tube is an endotracheal tube.

[0009] In prior art devices such as that described in GB2393399 (Nasir), and as illustrated in Figure 1, when an endotracheal tube is inserted through the airway tube, the endotracheal tube, instead of following its natural curve (which allows for correct insertion of the endotracheal tube into the laryngeal inlet), follows the curvature of the airway tube of the airway device. This often leads to the endotracheal tube, instead of entering the laryngeal inlet, sliding along the inside of the laryngeal cuff towards the tip of the device which can result in contact between the endotracheal tube and the larynx of the patient, and even insertion of the endotracheal tube into the oesophagus of the patient, both of which are undesirable.

[0010] However, in the present invention the airway device is provided with an intubating ramp which ensures that the endotracheal tube, when inserted through the airway tube, follows its natural curve, rather than the curve of the airway tube, and guides the endotracheal tube into the laryngeal inlet of the patient when the airway device is in situ in a patient.

[0011] The intubating ramp is provided on the internal wall of the dorsal side of the airway tube. Also described herein the intubating ramp is provided on the internal surface of the

dorsal side of the laryngeal cuff. Preferably the ramp is angled to ensure that when the tube is inserted through the airway tube when the device is in situ in a patient, it exists the device higher up in the anatomy of the patient and is guided into the laryngeal inlet of the patient.

[0012] In addition to the intubating ramp, the first end of the airway tube is of greater diameter and thus wider than the remainder of the airway tube. The internal surface of the ventral side of the airway tube is flattened rather than curved to provide this widening. This further enables the endotracheal tube, when inserted through the airway tube, to follow its natural curve, rather than the curve of the airway tube, and works in combination with the intubating ramp. Essentially what is created by the widening is a flaring at the first end of the airway tube as the airway tube emerges into the rear of the cuff

[0013] Preferably the intubating ramp is provided with a channel or groove. Preferably the channel or groove runs longitudinally along the full length of the intubating ramp from the first end to the second end of the longitudinal ramp. More preferably the intubating ramp is provided with a plurality of channels or grooves. The provision of the intubating ramp reduces the depth of the internal cavity of the laryngeal cuff, this means that should the device be sub-optimally inserted that there is risk that the airway of the patient could become partially occluded. The provision of the one or more channel(s) or groove(s) ensures the patency of the airflow through the airway device into the airway of the patient without compromising the effect of the ramp.

[0014] Preferably the tip of the laryngeal cuff is elongate. Preferably the tip of the laryngeal cuff is provided with a protrusion or bump on the back dorsal side thereof. The elongate nature of the tip of the laryngeal cuff along with the dorsal protrusion or bump both assist to provide an improved oesophageal seal when the airway device is in situ in the patient. By providing an improved oesophageal seal there is reduced risk of inflation of the stomach of the patient, and a reduced risk of regurgitation entering into the airway of the patient.

[0015] Preferably a side wall of the second end of the airway tube is provided with a supplementary gas inlet. The supplementary gas inlet allows for additional oxygen or other gas to be provided to the patient if required. A suitable supplementary gas inlet has been described in WO2011131974 (Miller).

[0016] The cuff is non-inflatable and is preferably pre-formed in a shape adapted to form an anatomical fit over the laryngeal framework of a patient.

[0017] Preferably the laryngeal cuff is pre-formed, pre-inflated with air or pre-filled with a suitable fluid. According to the invention, the laryngeal cuff is non-inflatable, however in the alternative, not belonging to the present invention, the laryngeal cuff can be inflatable.

[0018] In one alternative the airway device further comprises a buccal cavity stabiliser located on or around the airway tube between the laryngeal cuff and the second end of the tube. The buccal cavity stabiliser, if provided, may be formed from the same material as the cuff or from a

different material and assists in locating and maintaining the position of the device in use.

[0019] In a particularly preferred embodiment the buccal cavity stabiliser, if provided, is formed as an integral part of the airway tube, and further preferably the buccal cavity stabiliser, the airway tube and the laryngeal cuff are all formed as an integral unit.

[0020] In a further alternative no buccal cavity stabiliser is provided.

[0021] The Shore hardness of the various, parts, portions or components is an important feature of the invention. For example, the laryngeal cuff is preferably formed from a material with a Shore hardness on the A scale of 40 or less and more preferably 000 to 20, and most preferably 000 to 4.

[0022] Preferably the laryngeal cuff and a front, ventral part of the buccal cavity stabiliser, if provided, are formed from a material of substantially the same Shore hardness. This simplifies construction and ensures that all portions of the device that come into firm contact with the patient's soft tissue are relatively soft.

[0023] In a further preferred embodiment a back or dorsal part of the device and a front or ventral part of the device are formed from materials of different Shore hardness. This enables the dorsal portion to be made of a firmer material than the ventral portion.

[0024] Preferably the back or dorsal part of the device is formed from a material of Shore hardness less than 60 on the A scale, more preferably 25 to 45, and most preferably 30 to 40.

[0025] Preferably the device further incorporates a gastric tube passageway extending from the tip of the cuff to the second end of the airway device.

[0026] According to a second aspect of the disclosure there is provided an airway device for human or animal use comprising an airway tube having a first end and a second end, the first end of which is surrounded by a laryngeal cuff configured to fit over the laryngeal inlet of a patient when in situ, wherein the first end of the airway tube is of widened diameter or flared.

Brief Description of the Drawings

[0027] The invention will now be described, by way of example only, with reference to the accompanying drawings in which:-

Figure 1 illustrates a part cross-sectional view of the laryngeal cuff of the prior art;

Figure 2 illustrates a part cross-sectional view of the laryngeal cuff according to a first embodiment;

Figure 3 illustrates a front ventral perspective view of the laryngeal cuff according to a first

embodiment;

Figure 4 illustrates a side view of the laryngeal cuff according to a first embodiment;

Figure 5 illustrates a back dorsal view of the laryngeal cuff according to a first embodiment;

Figure 6 illustrates a side view of the supplementary gas inlet according to a first embodiment; and

Figure 7 illustrates a side view of the airway device according to a first embodiment.

Description of the Preferred Embodiments

[0028] Embodiments of the present invention are described below by way of example only. These examples represent the best ways of putting the invention into practice that are currently known to the applicant although they are not the only ways in which this could be achieved.

[0029] Referring to Figures 2 to 5, these illustrates an airway device 10 according to a first embodiment of the invention. The airway device 10 has an airway tube 12 having a first end 14 and a second end 16. The second end 16 optionally terminates in a 15mm or other connector 18 suitable for connection to an anaesthetic breathing system of conventional type. Formed around the first end 14 of the airway tube is a laryngeal cuff 20. In the embodiment illustrated the laryngeal cuff 20 is non inflatable and is adapted in its shape and contours to correspond with the laryngeal inlet region of a patient.

[0030] The first end 14 of the airway tube 12 is also provided with an intubating ramp 22 configured to direct an endotracheal tube (or another other applicable tube or device) inserted through the airway tube 12 into the laryngeal inlet of the patient when the airway device 10 is in situ within a patient. The intubating ramp 22 ensures that the endotracheal tube, when inserted through the airway tube, follows its natural curve, rather than the curve of the airway tube 12, and guides the endotracheal tube into the laryngeal inlet of the patient when the airway device 10 is in situ in a patient.

[0031] In the embodiment illustrated the intubating ramp 22 is provided on the internal wall of the back dorsal side of the airway tube 12. In the alternative, not belonging to the invention, the intubating ramp 22 can instead be provided on the internal surface of the back dorsal side of the laryngeal cuff 30.

[0032] In addition to the provision of intubating ramp 22, the first end 14 of the airway tube 12 is of greater diameter and thus wider than the remainder of the airway tube 12. In the embodiment illustrated the internal surface of the front ventral side 24 of the airway tube 12 is

flattened rather than curved to provide this widening. This further enables the endotracheal tube, when inserted through the airway tube 12, to follow its natural curve, rather than the curve of the airway tube 12 and works in combination with the intubating ramp 22.

[0033] In the embodiment illustrated the intubating ramp 22 is optionally provided with two channels 26, 28 that run longitudinally along the full length of the intubating ramp 22 from the first end to the second end thereof. The provision of the intubating ramp 22 reduces the depth of the internal cavity of the laryngeal cuff 20, this means that should the airway device 10 be sub-optimally inserted that there is risk that the airway of the patient could become partially occluded. The provision of the channels 26, 28 ensures the patency of the airflow through the airway device 10 into the airway of the patient without compromising the effect of the intubating ramp 22.

[0034] In the embodiment illustrated the tip 30 of the laryngeal cuff 20 is elongate compared to the prior art device illustrated in Figure 1. In addition the tip 30 of the laryngeal cuff 20 is provided with a protrusion or bump 32 on the back dorsal side thereof. The elongate nature of the tip 30 of the laryngeal cuff 20 along with the dorsal protrusion or bump 32 both assist to provide an improved oesophageal seal when the airway device 10 is in situ in the patient. By providing an improved oesophageal seal there is reduced risk of inflation of the stomach of the patient, and a reduced risk of regurgitation entering into the airway of the patient.

[0035] In addition in the embodiment illustrated a side wall of the second end 16 of the airway tube 12 has been provided with an optional supplementary gas inlet 34, more particularly the supplementary gas inlet 34 is formed as part of connector 18, however in the alternative it may be separate from connector 18. The supplementary gas inlet 34 allows for additional oxygen or other gas to be provided to the patient if required.

[0036] The laryngeal cuff is non-inflatable and in one alternative is formed from any suitable soft plastics material. By way of a preferred softness (hardness) range, on the Shore A scale of Hardness, a hardness of less than 40 for the face of the laryngeal cuff that contacts the laryngeal inlet is optimum. By way of a preferred range, a value on the same scale of 000 to 20 is preferred, with a particularly preferred range of 000 to 4. The softness of the laryngeal cuff can be further adapted by forming cavities or channels within the body of the cuff itself.

[0037] In a further alternative the laryngeal cuff may be pre-filled with a fluid such as air, or other non-toxic gas, or a non-toxic liquid. In this context the term fluid has a broad meaning and includes any suitable gas, liquid, vapour or combination thereof and will be determined and designed by an expert in this field of anatomy/anaesthesia in conjunction with the materials specialist. The laryngeal cuff will be constructed of such a material which will not allow nitrous oxide (anaesthetic gas) to diffuse through the material to any significant amount so that the extra luminal pressure is kept constant. It follows therefore that the laryngeal cuff should be substantially impermeable to the fluid with which is filled and to anaesthetic gases.

[0038] Alternatively, the laryngeal cuff can be formed from a soft, foamed material or can be

foam filled. In either case this provides a soft deformable but shaped surface around the face of the laryngeal cuff to engage over the anatomy of the larynx inlet region. Such a foam filled device will minimise any potential damage to the structures in that region whilst still providing a substantially complete seal.

[0039] Further in the alternative the laryngeal cuff is pre-filled during manufacture with a fluid in which case the lining of the cuff should be made from a material that does not absorb anaesthetic gases such as Nitrous Oxide, such that the pressure inside the cuff does not rise during use.

[0040] In another alternative the laryngeal cuff may be formed from a material which is adapted to absorb a liquid, such as water, mucous or blood or similar liquid material and in doing so to swell in size so as to confirm to the anatomical mucocartilagenous framework of the patient's laryngeal inlet. Such materials will be selected by the materials specialist but include CRM (cotton rayon mixes) as used in TAMPAX (RTM) tampons, or compressed Gel Foam 5.

[0041] In a further alternative, outside the invention, the laryngeal cuff could take the form of a conventional, inflatable laryngeal cuff. The technology to form an inflatable laryngeal cuff is well known and need not be described here.

[0042] Finally, in yet another alternative, the laryngeal cuff may be hollow, but not inflatable in the traditional sense of the word, and instead Positive Pressure Ventilation is employed to "inflate" and self-pressurise the laryngeal cuff.

[0043] Also in the embodiment illustrated a buccal cavity stabiliser 36 has been provided around the airway tube 12 between the laryngeal cuff 20 and the second end 16 of the airway tube 12. The buccal cavity stabiliser 36 assists in locating and maintaining the position of the airway device 10 in use.

[0044] In the embodiment illustrated the buccal cavity stabiliser 36 is formed as an integral part of the airway tube 12, and further preferably the buccal cavity stabiliser36 , the airway tube 12 and the laryngeal cuff 20 are all formed as an integral unit.

[0045] In an alternative no buccal cavity stabiliser is provided.

[0046] A gastric tube passageway 38, separate to the airway tube 12 is provided which runs from an opening in the second end of the device near the connector 18 if provided to an opening in the tip of the cuff 20. The gastric tube passageway 38 allows for any gastric aspirate to be detected in the event of passive regurgitation during use. It also provides a route for the insertion of small-bore gastric tubes (eg Freka Tubes).

[0047] The device may be constructed from any suitable plastics material as selected by the materials specialist. Latex-free medical grade silicone rubber is one preferred material. The

cuff should be soft in texture to avoid undue damage to the surrounding tissue. Other suitable materials for construction of this type of device include, but are not limited to, Poly Vinyl Chloride (PVC), Thermoplastic Elastomers such as the styrenic block copolymers (eg Styrene Butadiene Styrene (SBS), Styrene Ethylene Butylene Styrene (SEBS)), and Thermoplastic Olefin Blends (TPO), Thermoplastic PolyUrethanes (TPU), Copolyester (COPE), Polyether Block Amides (PEBAX) and foamed versions thereof, where appropriate.

[0048] A further important factor involved in the choice of a suitable material is transparency. Ideally the material or materials of construction should be substantially clear or transparent. This enables the anaesthetist or operator to see the inner lumen of the airway to check for blockages or other problems. Such transparent materials are known to the materials specialist.

REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

Patent documents cited in the description

- GB2393399A **[0002]** **[0009]**
- US20090090356A **[0005]**
- US5896858A **[0006]**
- WO2011131974A **[0015]**

PATENTKRAV

1. Luftvejsanordning (10) til brug for mennesker eller dyr, og som omfatter en luftvejsslange (12) med en første ende (14) og en anden ende (16), hvoraf den første ende (14) er omgivet af en ikke-oppustelig strubemanchet (20), der er udformet, når den er på plads, til at passe over indgangen til en patients strube, kendetegnet ved, at den første ende (14) af luftvejsslangen (12) er forsynet med en intubationsrampe (22) udformet til at dirigere en slange indført gennem luftvejsslangen (12) ind i indgangen til patientens strube, hvor på stedet luftvejsslangen (12) omfatter en indre væg, hvilken indre væg omfatter en ventral side og en dorsal side, og hvor den indre væg af den ventrale side (24) af den første ende (14) af luftvejsslangen (12) er mere flad end buet, og hvor den første ende af luftvejsslangen har en større diameter end resten af luftvejsslangen.

2. Luftvejsanordning ifølge krav 1, hvor intubationsrampen (22) er tilvejebragt på den indre væg af den dorsale side af luftvejsslangen.

3. Luftvejsanordning ifølge et hvilket som helst foregående krav, hvor intubationsrampen (22) er forsynet med en kanal (26, 28).

4. Luftvejsanordning ifølge krav 3, hvor intubationsrampen (22) har en første ende og en anden ende, og hvor kanalen (26, 28) løber på langs af en fuld længde af intubationsrampen fra den første ende til den anden ende af intubationsrampen.

5. Luftvejsanordning ifølge krav 3 eller krav 4, hvor intubationsrampen (22) er forsynet med en flerhed af kanaler (26, 28).

6. Luftvejsanordning ifølge et hvilket som helst foregående krav, hvor strubemanchetten (20) omfatter en spids (30), og hvor spidsen (30) af strubemanchetten (20) er aflang.

7. Luftvejsanordning ifølge et hvilket som helst foregående krav, hvor strubemanchetten (20) omfatter en spids (30) med en dorsal side bagtil og en ventral side fortil, og hvor spidsen (30) af strubemanchetten (20) er forsynet med et fremspring (32) på den dorsale side bagtil deraf.

8. Luftvejsanordning ifølge et hvilket som helst foregående krav, hvor en sidevæg af den anden ende af luftvejsslangen er forsynet med en supplerende gasindgang (34).

DRAWINGS

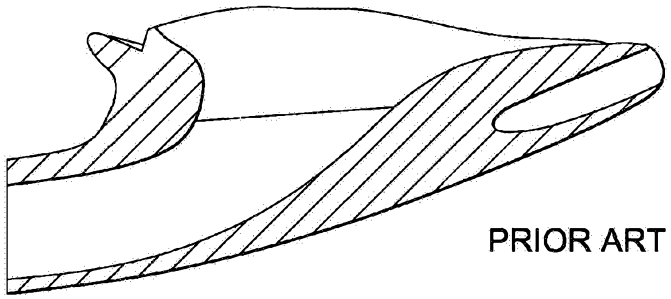

Figure 1

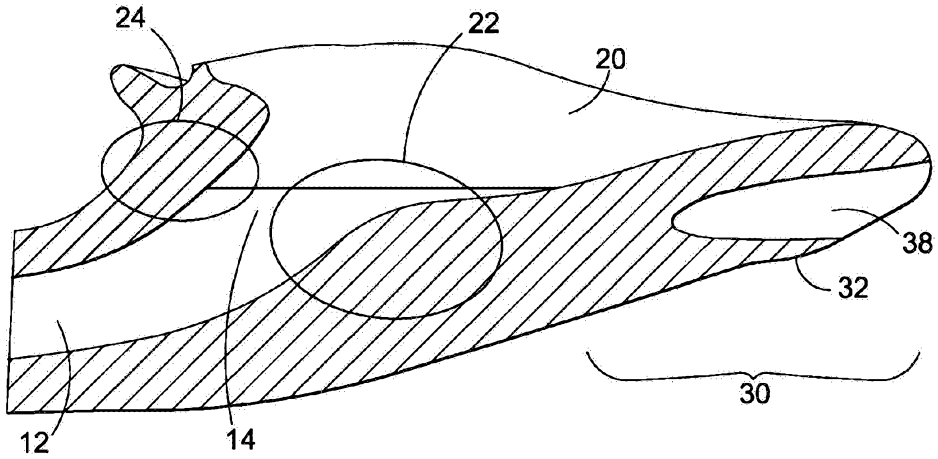

Figure 2

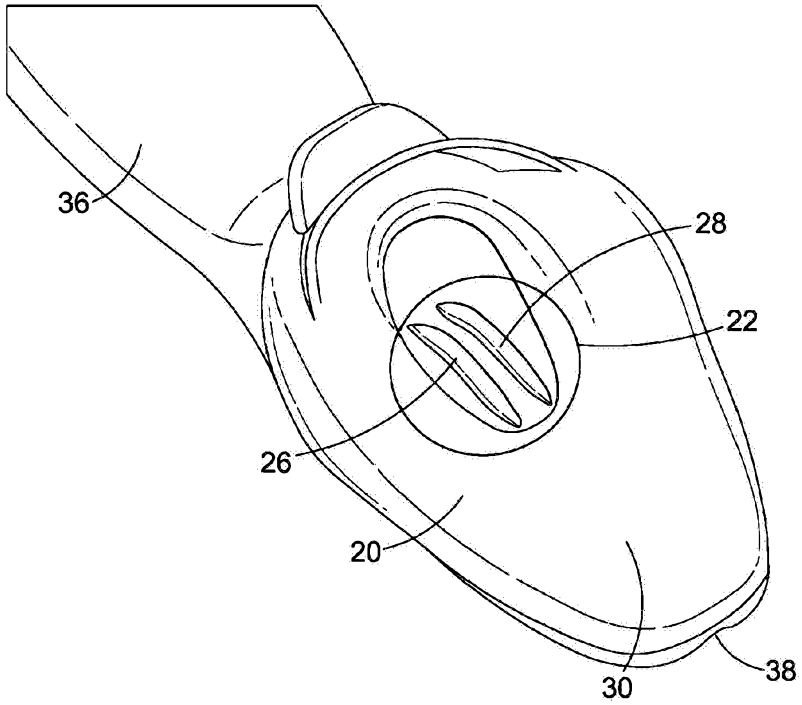

Figure 3

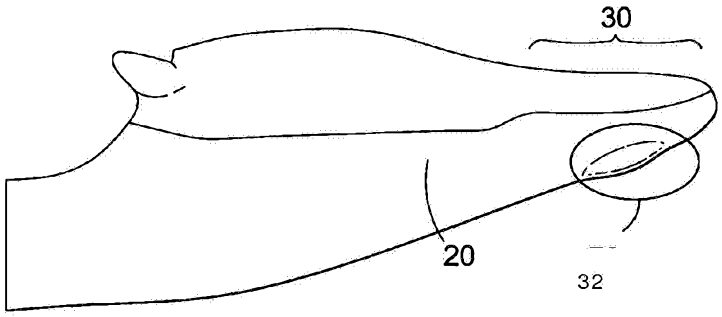

Figure 4

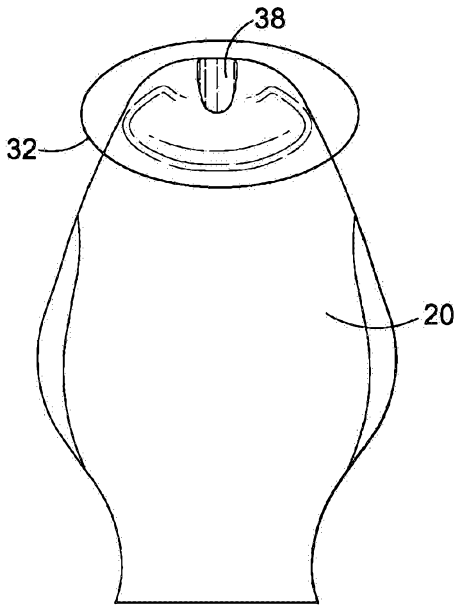

Figure 5

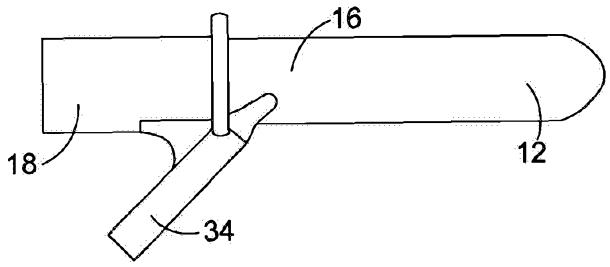

Figure 5

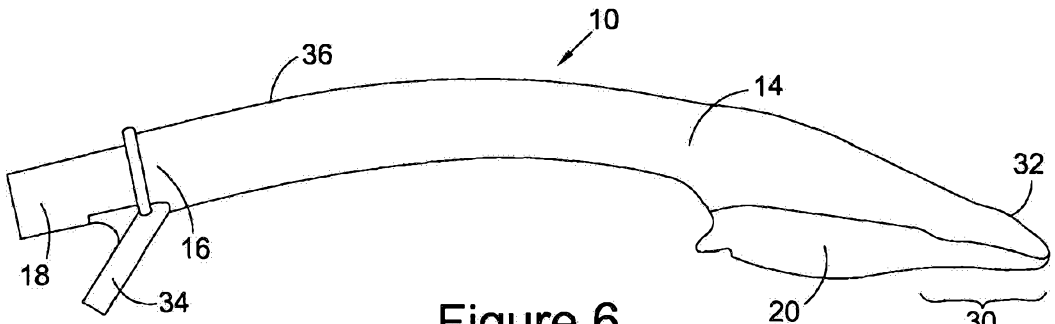

Figure 6